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IN THE UNITED STATES PATENT AND
TRADEMARK OFFICE

Application Number:

Filed:

Applicants: Lars Winther, Marc Key, Kristopher Buchanan, John Favuzzi, and
Benno Guggenheim

Title: Apparatus for Automated Processing Biological Samples

International Application No:PCT/US2003/040520, Filed 19 December 2003

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Examiner:

Assignee: DakoCytomation Denmark A/S

Attorney Docket: P145 US 01

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COVER SHEET*

FOR

A TRUE AND CORRECT COPY OF THE REPLY TO WRITTEN OPINION WITH

AMENDMENTS UNDER ARTICLE 34

* This Cover Sheet is provided for the convenience of Patent Office personnel, to indicate the new caption and title and thus minimize the risk of loss in the event documents are separated from the file.

IN THE UNITED STATES PATENT AND
TRADEMARK OFFICE
PCT BRANCH

In Re the Application of: DakoCytomation Denmark A/S

Inventors: Lars Winther, Marc Key, Kristopher Buchanan, John Favuzzi, and Benno Guggenheim

International Application Number: PCT/US03/40520

International Filing Date: December 19, 2003

Title: Apparatus for Automated Processing Biological Samples

Receiving Office: RO/US

**REPLY TO WRITTEN OPINION WITH
AMENDMENTS UNDER ARTICLE 34**

Pursuant to Article 34, the Applicant hereby amends the claims in the referenced application and the requests that the examiner consider the amendment prior to the International Preliminary Examination. Accordingly, the attached replacement sheets 17 - 25, and this amendment are submitted.

A. AMENDMENT

Please replace pages 17-20, as originally filed or previously amended with the attached replacement pages 17-25.

B. INDICATION OF DIFFERENCES

As required by Rule 11.14, and as set forth in paragraph 397 of the PCT Applicant's Guide, the following differences exist with respect to the claims as originally filed:

1. Claim 16, line 5 on replacement page 17 was amended to replace "exchanging" with "exchange".
2. Claim 38, line 25 on replacement page 19 was amended to replace "disfectants" with "disinfectants".

3. Claim 33, line 30 on replacement page 19 was amended to replace "carbondioxide" with "carbon dioxide".

4. New claims 40-71 are added in replacement page 20 and new pages 21-24.

New independent claim 40 is identical to claim 1 with an amendment that replaces "processing" in the first line of the claim with "staining".

New dependent claims 41 - 71 are similar to claims 2-32 respectively, with amendments to the dependencies to incorporate new independent claim 40 as well as removal of the improper multiple dependency form.

5. New page 25 includes the abstract as originally stated on old page 20.

The foregoing amendments do not go beyond the disclosure in the international application as filed and should be considered in establishing the first international examination report.

The applicant believes that lack of inventive step under PCT Article 33(3) relates to U.S. laws and rules regarding obviousness. Accordingly, the combination or modification of the prior art references in the manner suggested by the examiner was contrary to the accepted wisdom in the art at the time of the applicant's invention. MPEP §2143.01 states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

Because the facts derived from the references, as set forth below, there was no suggestion in the prior art to make the suggested combination or modification, the rejection is unsupported by the art and should be withdrawn.

Specifically, in Coville (U.S. Patent No. 4,695,430) the invention may be directed to testing for changes in optical characteristics of biological fluid samples. Coville does not discuss nor suggest use of a cover with a sample processing section as discussed in the Modlin reference.

The applicant further emphasizes that the prior art references do not individually, nor in combination, suggest the claimed invention. For example, claim 33 includes, *inter alia*, ventilating an interior space. This feature is not discussed in the prior art. Accordingly, the applicant believes that claims 1-71 are allowable.

C. CONCLUSION

The above changes should be considered and included in the examination of the application. A favorable examination report as to all pending claims is requested.

Dated this 31 day of March, 2005.

Respectfully Submitted,
SANTANGELO LAW OFFICES, P.C.

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15. An apparatus according to any of claims 1 to 14, wherein the at least one climate control device controls the ambient temperature of the air within the interior space.

16. An apparatus according to any of claims 1 to 15, wherein the climate control device
5 comprises a ventilation system configured to automatically exchange the air in the interior space.

17. An apparatus according to claim 16, wherein the ventilation system comprise a fan in an opening through which air may be exchanged.

10

18. An apparatus according to claim 17, further comprising at least one air manipulation device wherein said opening being provided with the characteristics of the air flowing into the apparatus, such as the air temperature, pressure, air flow rate and humidity.

15 19. An apparatus according to any of claims 1 to 18, wherein the climate control device comprises an exhaustion device capable of removing fumes from the interior space.

20. An apparatus according to any of claims 1 to 19, wherein the climate control device comprises a device capable of recycling air for humidity, temperature and toxic control, a
20 device capable of removing toxic elements from the air to be recycled, and/or a device capable of supplying humidity to the air to be recycled and/or a heater/cooling device capable of controlling the temperature of the air to be recycled.

25 21. An apparatus according to claim 20, wherein the device configured to recycle air comprises a filter capable of cleaning and/or humidifying the air.

22. An apparatus according to any of claims 19 to 21, wherein said exhaustion device is adapted to draw air from an outlet positioned below the level in which the at least one slide is accommodated.

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23. An apparatus according to any of claims 19 to 21, wherein said exhaustion device is adapted to draw air from an outlet positioned above the level in which the at least one slide is accommodated.

24. An apparatus according to any of claims 1 to 23, wherein said cover are provided with at least one seal element to provide an air tight seal between the cover means and the housing.

5 25. An apparatus according to any of claims 1 to 24, wherein an inlet is provided for supplying air into the interior space comprising at least one air inlet opening in the housing frame, and wherein an air manipulation device are provided in said inlet means for adapting the inflowing air with predetermined characteristics.

10 26. An apparatus according to claim 25, wherein said air manipulation device comprises an a humid filter device wherein the inlet air is drawn through said humid filter device to ensure high and uniform humidity in the chamber.

15 27. An apparatus according to claim 25, wherein the air manipulation device controls humidity by spraying water droplets or having a water surface.

28. An apparatus according to claim 25, wherein the air manipulation device comprises an air recycling device where the recycled air is drawn through filters to remove fumes and filters to adjust the humidity.

20 29. An apparatus according to claim 25, wherein the air manipulation device controls the humidity to never be below a predetermined level, to prevent drying out of the sample.

25 30. An apparatus according to claim 25, wherein the air manipulation device comprises an air additive supply device by which disinfectants, UV protectants or other compounds may be added to the inlet air to prevent microbial growth or discolouring.

31. An apparatus according to claim 25, wherein the air manipulation device comprises an air additive supply arranged for addition of fluids from the group comprising reagents, neutral gas, oxygen, carbondioxide, nitrogen, water droplets, and formamide.

30 32. An apparatus according to any of claims 1 to 31, wherein the apparatus comprises at least one sensor device to register one or more parameters of the air in interior space of

the apparatus, said sensors being arranged in the vicinity of the cover means and/or in the vicinity of the sample carriers on a carrier rack assembly.

33. A method of automatically processing one or more biological samples accommodated on a carrier member, such as a slide, by applying a predetermined amount of reagents in a predetermined sequence according to a processing protocol in an automatic sample processing apparatus, comprising the steps of:
5 measuring at least one air characteristic inside an interior space in which at least one carrier member is provided inside a cover enclosing the samples accommodated in the apparatus, and
10 ventilating said interior space and controlling said apparatus according to a predetermined processing environment defined in a processing control procedure, said ventilation including exchanging air through at least one air inlet and air outlet.

15 34. A method according to claim 33, wherein the inlet air is drawn through a humid filter device of the air manipulation device to ensure high and uniform humidity in the chamber.

20 35. A method according to claim 33, wherein the humidity is controlled by spraying water droplets or having a water surface.

36. A method according to claim 33, wherein recycled air is drawn through filters to remove fumes and filters to adjust the humidity.

25 37. A method according to claim 33, wherein the humidity is controlled to never be below a predetermined level, to prevent drying out of the sample.

38. A method according to claim 33, wherein disinfectants, UV protectants or other compounds may be added to the inlet air to prevent microbial growth or discolouring.

30 39. An apparatus according to claim 33, wherein the air manipulation device comprises air additive supply device arranged for addition of fluids from the group comprising reagents, neutral gas, oxygen, carbondioxide, nitrogen, water droplets, and formamide.

40. An apparatus for automatic staining of at least one biological sample accommodated on a carrier member, such as a slide, by applying a predetermined amount of reagents in a predetermined sequence according to a processing protocol, comprising:

- 5 a housing frame;
- at least one sample processing section for accommodating at least one carrier member for a sample, said at least one sample processing section being provided within said housing;
- 10 a cover protecting said at least one sample processing section in said housing, said cover enclosing the sample processing section and defining an interior space between the housing and the cover;
- at least one climate control device configured to control the environment within 15 said interior space; and
- a sensor device providing feedback signals to the climate control means.

41. An apparatus according to either one of claim 1 or 40, wherein the sensor device is adapted to sense at least one climate parameter from the group comprising temperature, 20 pressure, humidity, airspeed and the presence of toxic elements in fume.

42. An apparatus according to either one of claim 1 or 40, wherein the sensor device comprises internal sensors located inside the interior space.

25 43. An apparatus according to either one of claim 1 or 40, wherein the sensor device comprises external sensors located outside the interior space, such as at or inside an air inlet/outlet manifold, in a laboratory facility accommodating the apparatus, or outside the building accommodating the laboratory.

30 44. An apparatus according to either one of claim 1 or 40, wherein the cover comprises at least one openable hood.

45. An apparatus according to either one of claim 1 or 40, wherein the cover is an integrated part of the apparatus.

46. An apparatus according to either one of claim 1 or 40, wherein the cover comprises a plurality of covers arranged to cover a plurality of sections of the apparatus, such as at least one biological sample accommodated on a carrier in the at least one processing section.

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47. An apparatus according to claim 46, wherein a plurality of interior spaces of the apparatus is defined by said plurality of covers, each interior space including at least one section arranged for comprising at least one sample on a carrier and/or at least one section arranged for comprising at least one reagent in a container.

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48. An apparatus according to claim 47, wherein the at least one climate control device is arranged to control the climate in each interior space, comprising at least one sample on a carrier, according to a sample processing protocol defined for that particular sample.

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49. An apparatus according to claim 48, wherein the at least one climate control device receives input signals from internal and/or external sensors, and is arranged to control the climate in each interior space, according to the input signals.

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50. An apparatus according to claim 47, wherein the at least one climate control device is connected for data communication with a data processing device, such as a computer, wherein the protocol for the processing of the particular sample is stored, and where from control data are provided to the climate control means.

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51. An apparatus according to either one of claim 1 or 40, wherein the at least one climate control device controls at least the pressure and ensures a slight sub-pressure within the interior space.

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52. An apparatus according to either one of claim 1 or 40, wherein the at least one climate control device controls at least the pressure and ensures a slightly higher pressure within the interior space.

53. An apparatus according to either one of claim 1 or 40, wherein the at least one climate control device includes humidity control within the interior space.

54. An apparatus according to either one of claim 1 or 40, wherein the at least one climate control device controls the ambient temperature of the air within the interior space.

5 55. An apparatus according to either one of claim 1 or 40, wherein the climate control device comprises a ventilation system configured to automatically exchange the air in the interior space.

10 56. An apparatus according to claim 55, wherein the ventilation system comprise a fan in an opening through which air may be exchanged.

57. An apparatus according to claim 56, further comprising at least one air manipulation device wherein said opening being provided with the characteristics of the air flowing into the apparatus, such as the air temperature, pressure, air flow rate and humidity.

15 58. An apparatus according to either one of claim 1 or 40, wherein the climate control device comprises an exhaustion device capable of removing fumes from the interior space.

20 59. An apparatus according to either one of claim 1 or 40, wherein the climate control device comprises a device capable of recycling air for humidity, temperature and toxic control, a device capable of removing toxic elements from the air to be recycled, and/or a device capable of supplying humidity to the air to be recycled and/or a heater/cooling device capable of controlling the temperature of the air to be recycled.

25 60. An apparatus according to claim 59, wherein the device configured to recycle air comprises a filter capable of cleaning and/or humidifying the air.

30 61. An apparatus according to claim 58, wherein said exhaustion device is adapted to draw air from an outlet positioned below the level in which the at least one slide is accommodated.

62. An apparatus according to claim 58, wherein said exhaustion device is adapted to draw air from an outlet positioned above the level in which the at least one slide is accommodated.

5 63. An apparatus according to either one of claim 1 or 40, wherein said cover is provided with at least one seal element to provide an air tight seal between the cover means and the housing.

10 64. An apparatus according to either one of claim 1 or 40, wherein an inlet is provided for supplying air into the interior space comprising at least one air inlet opening in the housing frame, and wherein an air manipulation device is provided in said inlet means for adapting the inflowing air with predetermined characteristics.

15 65. An apparatus according to claim 64, wherein said air manipulation device comprises a humid filter device wherein the inlet air is drawn through said humid filter device to ensure high and uniform humidity in the chamber.

20 66. An apparatus according to claim 64, wherein the air manipulation device controls humidity by spraying water droplets or having a water surface.

67. An apparatus according to claim 64, wherein the air manipulation device comprises an air recycling device where the recycled air is drawn through filters to remove fumes and filters to adjust the humidity.

25 68. An apparatus according to claim 64, wherein the air manipulation device controls the humidity to never be below a predetermined level, to prevent drying out of the sample.

69. An apparatus according to claim 64, wherein the air manipulation device comprises an air additive supply device by which disinfectants, UV protectants or other compounds 30 may be added to the inlet air to prevent microbial growth or discoloring.

70. An apparatus according to claim 64, wherein the air manipulation device comprises an air additive supply arranged for addition of fluids from the group comprising reagents, neutral gas, oxygen, carbon dioxide, nitrogen, water droplets, and formamide.

71. An apparatus according to either one of claim 1 or 40, wherein the apparatus comprises at least one sensor device to register one or more parameters of the air in interior space of the apparatus, said sensors being arranged in the vicinity of the cover
5 means and/or in the vicinity of the sample carriers on a carrier rack assembly.

ABSTRACT

The present invention concerns an apparatus for automatic processing at least one biological sample accommodated on a carrier member, such as a slide by applying a 5 predetermined amount of reagents in a predetermined sequence according to a processing protocol, said apparatus comprising: a housing frame; at least one processing section for accommodating at least one slide, the at least one processing section is provided within the housing; a hood cover protecting the at least one processing section in said housing; wherein the hood cover completely encloses the processing section defining an interior 10 space; and wherein the apparatus further comprises climate control device provided to control the environment within the interior space.

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In Re the Application of: DakoCytomation Denmark A/S

Inventors: Lars Winther, Marc Key, Kristopher Buchanan, John Favuzzi, and Benno Guggenheim

International Application Number: PCT/US03/40520

International Filing Date: December 19, 2003

Title: Apparatus for Automated Processing Biological Samples

Receiving Office: RO/US

CERTIFICATE OF EXPRESS MAILING

I, Cheryl A. Swanson, hereby certify to the truth of the following items:

1. I am an employee of Santangelo Law Offices, P.C., 125 South Howes, Third Floor, Fort Collins, Colorado 80521.
2. I have this day deposited the attached Reply to Written Opinion with Amendments under Article 34, and replacement pages 17-25 with the United States Postal Service as "Express Mail", with sufficient postage, for mailing to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

Dated this 31 day of March, 2005.

Cheryl A. Swanson
Cheryl A. Swanson

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IN THE UNITED STATES PATENT AND
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Application Number:

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Applicants: Lars Winther, Marc Key, Kristopher Buchanan, John Favuzzi, and
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Original US Applications: 60/435,601, Filed 20 December 2002

TC/A.U:

Examiner:

Assignee: DakoCytomation Denmark A/S

Attorney Docket: P145 US 01

Customer No.: 33549

CERTIFICATE OF EXPRESS MAILING

I, Cheryl A. Swanson, hereby certify to the truth of the following items:

1. I am an employee of Santangelo Law Offices, P.C., 125 South Howes, Third Floor, Fort Collins, Colorado 80521.

2. I have this day deposited the attached true and correct copy of the Reply to Written Opinion with Amendments Under Article 34, along with a cover sheet with the United States Postal Service as "Express Mail" for mailing to: Mail Stop PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Dated this 16th day of June, 2005.

Cheryl A. Swanson
Cheryl A. Swanson